

[59] WE CLAIM:

1. A system comprising:
a pump coupled to a reservoir;
a catheter coupled to the pump and adapted for delivering a therapeutic agent to a cerebrospinal fluid of a patient; and
an injectable composition comprising gabapentin housed in the reservoir and deliverable through the catheter in an amount effective to treat epilepsy in the patient when administered to the cerebrospinal fluid of the patient.
2. The system of claim 1, wherein the composition comprises between about 0.1 mg/mL and about 100 mg/mL gabapentin.
3. The system of claim 2, wherein the composition comprises between about 10 mg/mL to about 80 mg/mL gabapentin.
4. The system of claim 2, wherein the solution comprises about 80 mg/mL gabapentin.
5. The system of claim 2, wherein the solution comprises between about 20 mg/ml and about 40 mg/ml gabapentin.
6. The system of claim 2, wherein the solution comprises between about 30 mg/ml gabapentin.
7. The system of claim 1, wherein the composition is an aqueous solution.
8. The system of claim 7, wherein the aqueous solution comprises sodium chloride.
9. The system of claim 8, wherein the solution comprises about 0.9% (w/v) sodium chloride.

10. The system of claim 8, wherein the solution comprises an amount of sodium chloride such that the solution is substantially isotonic with the cerebrospinal fluid.
11. The system of claim 7, wherein the solution has a pH between about 4 and about 9.
12. The system of claim 11, wherein the solution has a pH between about 5, and about 7.
13. The system of claim 12, wherein the solution has a pH between about 5.5 and about 6.5.
14. The system of claim 7, wherein the solution comprises essentially no preservatives.
15. The system of claim 14, wherein the solution comprises essentially no buffers.
16. The system of claim 1, wherein the composition comprises less than about 5% (w/v) gabapentin lactam.
17. The system of claim 7, wherein the solution has a pH between about 5.5 and about 6.5, and comprises essentially no preservatives, essentially no buffers, and less than about 5% (w/v) gabapentin lactam.
18. The system of claim 1, wherein the pump is an implantable pump.
19. The system of claim 1, wherein the composition further comprises one or more additional anti-epileptic agent.

20. The system of claim 19, wherein the one or more additional antiepileptic agent is selected from the group consisting of:
a hydantoin, a barbiturate, a deoxybarbiture, an iminostilbene, a succinimide, valproic acid, an oxazolidinedione, a benzodiazepine, and a phenyltrizins.
21. The system of claim 19, wherein the one or more additional antiepileptic agent is selected from the group consisting of:
phenytoin, mephenytoin, ethotoin, phenobarbital, mephobarbital, primidone, carbamazepine, ethosuximide, methsuximide, phensuximide, valproate, triemethadione, paramethadione, diazepam, clonazepam, midazolam, baclofen, thyrotropin-releasing hormone, adenosine, and lamotrigine, or a pharmacologically acceptable salt thereof.
22. The system of claim 1, wherein the composition further comprises baclofen.
23. The system of claim 22, wherein the composition comprises between about 50 µg/ml and about 3000 µg/ml baclofen.
24. The system of claim 1, wherein the composition further comprises midazolam.
25. The system of claim 24, wherein the composition comprises between about 1 mg/ml and about 5 mg/ml midazolam.
26. The system of claim 1, wherein the composition further comprises valproate Na.
27. The system of claim 26, wherein the composition comprises between about 1 mg/ml and about 100 mg/ml valproate Na.
28. A system comprising:
a pump coupled to a reservoir;

a catheter coupled to the pump and adapted for delivering a therapeutic agent to a brain tissue of a patient; and
an injectable composition comprising gabapentin housed in the reservoir and deliverable through the catheter in an amount effective to treat epilepsy in the patient when administered to the brain tissue of the patient.

29. A method for treating a epilepsy in a patient in need thereof, the method comprising:
administering to a cerebrospinal fluid of the patient a composition comprising gabapentin in an amount effective to treat epilepsy in the patient, wherein the composition is administered by a pump system.
30. The method of claim 29, wherein the composition is administered to the patient's cerebrospinal fluid.
31. The method of claim 30, wherein the composition is administered to the patient's spinal cord.
32. The method of claim 30, wherein the composition is administered by infusing gabapentin into the subarachnoid space around the brain.
33. The method of claim 30, wherein the composition is administered intracerebroventricularly.
34. The method of claim 29, wherein the composition is administered to directly to the patient's brain tissue.
35. The method of claim 29, further comprising selecting a patient with a history of seizures selected from the group consisting of:
auras, simple-partial seizures, jacksonian seizures, complex partial seizures, generalized seizures, infantile spasms, absence-seizures, generalized-tonic-clonic-

seizures, atonic seizures, myoclonic seizures, febrile-seizures, status-epilepticus, epilepsia-partialis-continua, and combinations thereof.

36. The method of claim 29, wherein the epilepsy is intractable epilepsy.
37. The method of claim 29, wherein gabapentin is administered at a daily dose of between about 0.1 mg and about 200 mg.
38. The method of claim 29, wherein gabapentin is administered at a daily dose of between about 1 mg and about 150 mg
39. The method of claim 38, wherein gabapentin is administered at a daily dose of between about 2 mg and about 60 mg.
40. The method of claim 29, wherein gabapentin is administered at a daily dose of greater than about 25 mg.
41. The method of claim 29, wherein gabapentin is administered at a daily dose of less than about 25 mg.
42. The method of claim 41, wherein gabapentin is administered at a daily dose of between about 0.1 mg and about 10 mg.
43. The method of claim 29, wherein the pump is an implantable pump.
44. The method of claim 43, wherein the patient controls the amount of gabapentin administered.
45. The method of claim 44, wherein the patient controls the amount of gabapentin administered by way of a patient-controlled activator.

46. The method of claim 29, further comprising administering to the patient one or more additional anti-epileptic agent.
47. The method of claim 46, wherein the one or more additional anti-epileptic agent is selected from the group consisting of:
a hydantoin, a barbiturate, a deoxybarbiture, an iminostilbene, a succinimide, valproic acid, an oxazolidinedione, a benzodiazepine, and a phenyltriazins.
48. The method of claim 46, wherein the one or more additional antiepileptic agent is selected from the group consisting of:
phenytoin, mephenytoin, ethotoin, phenobarbitol, mephobarbitol, primodone, carbamazepine, ethosuximide, methsuximide, phensuximide, valproate, triemethadione, paramethadione, diazepam, clonazepam, midazolam, baclofen, thyrotropin-releasing hormone, adenosine and lamotrigine, or a pharmacologically acceptable salt thereof.
49. The method of claim 46, wherein the one or more additional anti-epileptic agent is administered to the patient's cerebrospinal fluid or brain tissue.
50. The method of claim 49, wherein at least one of the one or more additional antiepileptic agent is baclofen or a pharmacologically acceptable salt thereof.
51. The method of claim 50, wherein the baclofen or the pharmacologically acceptable salt thereof is administered at a daily dose of between about 50 µg and about 1500 µg.
52. The method of claim 49, wherein at least one of the one or more additional antiepileptic agent is midazolam or a pharmacologically acceptable salt thereof.

53. The method of claim 52, wherein the midazolam or the pharmacologically acceptable salt thereof is administered at a daily dose of between about 0.1 mg and about 5 mg.
54. The method of claim 49, wherein at least one of the one or more additional antiepileptic agent is valproate Na.
55. The method of claim 55, wherein the valproate Na is administered at a daily dose of between about 5 mg and about 100 mg.
56. A method for treating epilepsy in a patient in need thereof, the method comprising:
administering to a cerebrospinal fluid of the patient a composition comprising gabapentin in an amount effective to treat epilepsy in the patient, wherein gabapentin is administered at a daily dose of greater than about 25 mg and wherein the patient experiences substantially no somnolence, dizziness, ataxia, or motor weakness due to the gabapentin.
57. A method for treating epilepsy in a patient in need thereof, the method comprising:
administering to a brain tissue of the patient a composition comprising gabapentin in an amount effective to treat epilepsy in the patient, wherein gabapentin is administered at a daily dose of greater than about 25 mg and wherein the patient experiences substantially no somnolence, dizziness, ataxia, or motor weakness due to the gabapentin.
58. A method for preparing a system of claim 1, comprising adding the injectable composition to the reservoir.
59. A method for preparing a system of claim 28, comprising adding the injectable composition to the reservoir.